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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,659	04/18/2001	Michel Chevalier	01-057	3396

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MCDONNELL BOEHNEN HULBERT & BERGHOFF  
300 SOUTH WACKER DRIVE  
SUITE 3200  
CHICAGO, IL 60606

EXAMINER
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WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 05/07/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

09/744,659

Applicant(s)

CHEVALIER, MICHEL

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-21, 28 and 29 is/are allowed.
- 6) ☒ Claim(s) 11-17, 22, 24-27, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
- 1. ☐ Certified copies of the priority documents have been received.
  - 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☒ Interview Summary (PTO-413) Paper No(s). 13.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The Amendment filed February 24, 2003 (Paper No. 11) in response to the Office Action of November 6, 2002 is acknowledged and has been entered. Claims 11-31 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

To clarify the record in applicants response (Paper No. 11) reference is made to an Appendix A showing an SDS-Page gel. The Appendix A was not submitted with the response by applicant, therefore it has not been made of record.

### ***Specification***

Applicants amendments to the specification correcting informalities such as the addition of an abstract, the inclusion of priority information and the addition of a description of the figures is acknowledged.

### ***Claim Rejections - 35 USC § 112***

The rejection of claims 11-19 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn** in view of applicants assertion. "In fact, naturally occurring trimers are known not to contain inter-chain disulfide linkages." Therefore, according to applicants assertion naturally occurring virus as well as intergraded virus from a

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chronically infected cell will produce gp160 without interchain disulfide bonds as opposed to recombinantly produced gp160 which contains interchain disulfide linkages.

The rejection of claims 11-19 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement **is withdrawn** in view of applicants amendment to the claims. Applicants have amended the claim in such a way that it is clear the method steps must be carried out in a particular sequence and the claims have been amended to being a composition in conjunction with and adjuvant.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11-17, 22, 24, 25, 26, 27, 30 and 31 rejected under 35 U.S.C. 102(b) as being anticipated by Samgadharan et al. (U.S. Pat. NO. 5,122,468) as evidenced by the product information found in the Advanced Bioscience Catalog (see Product specification Viral antigens).

The instant invention is drawn to a composition comprising a trimer which has the qualities of being able to of being able to bind CD4, binding to neutralizing gp120 antibody, binding to gp41 antibody and having no interchain disulfide bridges. Applicant has asserted that "In fact, naturally occurring trimers are known not to contain inter-chain disulfide linkages." The

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amendments to the claims remove the limitation that the that the purified trimer is either naturally occurring (as it would in nature) or recombinant. The present claims do not limit the source of gp160 so this can include gp160 which is expressed from a cell line that is expressed from a cell line which is chronically infected with the virus. These cell lines are neither naturally occurring nor recombinant. Because as applicant asserts naturally occurring gp160 does not contain interchain disulfide bridges, the ordinary artisan would then not expect the product from a chronic virally infected cell to contain interchain disulfide bridges as well. The natural life cycle of the virus requires integration into the cell genome from which the product is then transcribed before further processing.

Sarnagadharan et al. discloses the production and purification of gp160 from a chronically infected cell line. The gp160 is purified via affinity chromatography (see column 4, lines 42-47) using anti gp41 antibody. Product information from Advanced Bioscience Catalog indicates that gp160 purified from the same chronically infected cell line with the same affinity purification steps results in gp160 oligomer that comprises mostly trimers and dimers. Because the ability to bind antibodies is depended on structure, the trimers produced by the methods of Sarnagadharan et al. will have the requirement of binding gp120 neutralizing antibodies, they have been shown to bind gp41 antibodies in the purification step and because they are produced from a chronic virally infected cell they would not have interchain disulfide bonding. Therefore, the instant invention is anticipated by Sarnagadharan et al.

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***Claim Objections***

Claim 23 is objected to because of the following informalities: The claim is dependent on a rejected claim. Appropriate correction is required.

***Conclusion***

Claims 16-21, 28, 29 directed to the method of producing the trimmer are allowable.

Claims 11-17, 22, 23-27, 30 and 31 are rejected.

Claim 23 is objected to

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294.

The examiner can normally be reached M-F, 8:30 am - 5 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Ulrike Winkler, Ph.D.



JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
5/5/03